

Trial EudraCT number 2017-001395-38

Sponsor: Azienda USL della Valle d'Aosta

Title of the trial: Treatment of Metastatic prostate cancer castration resistant (mCRPC) with 223RaCl₂: response evaluation with a novel tracer 68Ga-PSMA PET molecular imaging (CALIPSO)

Date of End of trial in Italy : 06 December 2019 (Last Patient Last Visit)

Number of patient recruited: 5

Sponsor's justification of Premature end of this trial:

The premature end of this trial is motivated by several concomitant factors: the slowness of recruitment (probably also due to the known regulatory changes for Xofigo) together with the fact that only one of the satellite centers has completed the agreement with the promoter center, but any one recruited patient whilst we, as coordinators of the study, have recruited only half of the expected patients. Furthermore, Bayer has decided to suspend the financial support to the study which allowed the coverage of the production costs of the 68Ga-PSMA radiopharmaceutical only: for this reason the continuation of the study in most of the centers would no longer be feasible. In light of these problems, we are therefore forced to conclude the Calipso study early.

Two patients (N. 01 and 02) completed the six cycles of therapy and underwent the three 68Ga-PSMA PET/CT, both patients showed progression disease at the EoT PET.

One patient (N. 03) completed only two cycles of therapy and treatment was stopped because of a "bone event" that needed Radiotherapy (only basal 68Ga-PSMA PET/CT was performed).

One patient (N. 04) completed four cycles of therapy , treatment was stopped because of progression disease (only basal 68Ga-PSMA PET/CT was performed, no further imaging was performed for premature end of this trial).

One patient (N.05) completed two cycles of therapy, treatment was stopped because of progression disease and clinical condition (only basal 68Ga-PSMA PET/CT was performed, no further imaging was performed for premature end of this trial).

No SAE were reported, both for IMP for imaging (68Ga-PSMA) for imaging, both for 223-Radium.

Overall survival (time from first cycles of 223-Radium treatment to death due to any cause) was less than one year for the three patients that did not complete six cycles of therapy (N.03, 04, 05).

Overall survival for the two patients that completed six cycles of therapy was approximately 20 months.